VERMONT

# Vermont Health Access
# Pharmacy Benefit Management Program
# *DUR Board Meeting Minutes: 04/01/08*

**Board Members:**

Michael Scovner, M.D., Chair
Andrew Miller, R. Ph.
Cheryl Gibson, M.D.
Norman Ward, M.D.
Stuart Graves, M.D.
Lynne Vezina, R.Ph.
Virginia Hood, M.D.

**Staff:**

Ann Rugg, OVHA
Diane Neal, R.Ph., (MHP)
Robin Farnsworth, OVHA
Nancy Miner, (MHP)
Stacey Baker, OVHA
Jennifer Mullikin, OVHA
Nancy Hogue, Pharm.D. (MHP)
Judy Jamieson, OVHA

**Guests:**

Amy Finn, Merck
Art McNulty, Forest
Bill Eicholzier, Sanofi-Aventis
Carl Possidente, Pfizer
Charron Long, Allergan, Inc
Ellen K Flatley, GSK
Eric Rappaport, Eli Lilly
Glenn E. Dooley, Sr, Sanofi-Aventis
Keith White, Genentech
Laurie Ritchie, DSI
Lyndon Braun, Santarus
Marie Sanchirico, Sanofi-Aventis
Mark Kaplan, Abbott
Matt Badalucco, Merck
Natalie Prairie, Forest
Robert Mcsparrey, Bristol-Myers Squibb
Scott Mosher, GSK
Steve Berardino, Amgen
Terry Lalancette, GSK
Ward Bennett, Ortho Biotech

Michael Scovner, M.D. Chair, called the meeting to order at 7:04 p.m. at the DUR Board meeting site in Williston.

## 1. Executive Session:

- An executive session was held from 6:30 until 7:00 p.m. to discuss Medicaid OBRA'90/Supplemental Rebates and Agreements as provided by 33 VSA § 1998(f)(2).

## 2. Introductions and Approval of DUR Board Minutes:

- Introductions were made around the table.
- The February 2008 minutes were accepted as printed.

*Public Comment*: No public comment.

## 3. OVHA Pharmacy Administration Updates: *Ann Rugg - Deputy Director, OVHA*

- Nancy Hogue, Pharm.D., was introduced as the new MedMetrics Health Partners Account Manager, joining Diane Neal, R,Ph., (Clinical Account Manager) and Nancy Miner, CPhT (Program Representative) on site in Williston at the OVHA offices.

## 4. Medical Director Update:

Clinical Programs Update: No updates to report. Medical Director absent.

Prescriber Comments: No comments to report**.**

**5. Follow-up items from Previous Meeting:** *Diane Neal, R.Ph., MedMetrics Health Partners (MHP)*

- Cough and Cold Products in Children < 2 years old:
  At the request of the DUR board at the February meeting, input from the pediatrician community was sought on the issue of cough and cold products in children < 2 years old. It was recommended that PA be required for children < 2 years old for all cough and cold products (brand and generic). Prescribers will be reminded of the FDA safety alert when requesting PA.

*Public Comment:* No public comment.

**Board Decision:** Revised criteria were presented and voted upon later in the meeting with the Tussionex® discussion which is also in the Cough and Cold managed category.

- Desmopressin (DDAVP) Spray:
  In response to a desmopressin nasal preparation FDA alert presented several meetings ago, a summary of safety information for all dosage forms was presented. It was recommended that all nasal preparations require prior authorization for all ages and that requests for the diagnosis or indication of (1) Diabetes Insipidus, (2) hemophilia type A, or (3) Von Willebrand disease be approved. Desmopressin intranasal formulations would not be approved for the treatment of primary nocturnal enuresis (PNE) due to safety risks of hyponatremia. Oral tablets may be prescribed for this indication.

*Public Comment:* No public comment.

**Board Decision:** The Board approved the MHP recommendations as described.

- Erythropoiesis Stimulating Agents:
  The additional FDA alert describing 2 more studies showing increased mortality and tumor progression in oncology patients receiving ESAs was presented. The FDA Oncology Drugs Advisory Committee recommendations were also presented.

*Public Comment: Steve Berardino, Amgen* – Commented that the manufacturers are encouraging physicians to use ESAs conservatively and that there has been a significant drop in utilization.

**Board Decision:** The DUR Board will wait for the FDA to act on the ODAC recommendations before further actions are determined. It was decided that there is no need to send a planned prescriber letter at this time.

- Zetia® /Vytorin®:
  The New England Journal of Medicine editorials responding to the ENHANCE study were discussed. No action was recommended regarding the PDL placement of cholesterol lowering drugs.

*Public Comment:* No public comment.

**Board Decision:** None needed.

6. **Clinical Update: Drug Reviews** *Diane Neal, R.Ph.( MHP)*
(Public comment prior to Board action)

Note: All drug/criteria decisions will be reflected in the next PDL and/or Clinical Criteria update.

- Astelin® (azelastine) Nasal Spray: Not recommended for addition to the PDL. Coverage would require PA with the criteria for approval being that the diagnosis or indication for the requested medication is allergic rhinitis and the patient has had a documented side effect, allergy, or treatment failure to loratadine (OTC), cetirizine OTC or a preferred nasal glucococorticoid. A quantity limit of 2 bottles/month was recommended.

*Public Comment:* No public comment.

**Board Decision:** The Board approved the MHP recommendations as described with the quantity limit reduced to 1 bottle/25 days.

- Azor® (amlodipine/olmesartan): Not recommended for addition to the PDL. Coverage would require PA with the criteria for approval being that the patient has been started and stabilized on the requested medication (Note: samples are not considered adequate justification for stabilization) or the patient has had a documented side effect, allergy, or treatment failure to an angiotensin converting enzyme inhibitor (ACEI), an ACEI combination or any other angiotensin receptor blocker (ARB) or ARB combination and the patient has had a documented side effect, allergy, or treatment failure to Exforge® or to amlodipine and valsartan as separate entities and the patient is unable to use Benicar® and amlodipine as separate agents. A quantity limit of one tablet/day was recommended.

*Public Comment: Laurie Ritchie, Sanofi-Aventis* – Asked for clarification around pricing.

**Board Decision:** The Board approved the MHP recommendations as described with "started and stabilized" removed as a criteria for approval since the individual components of the medication are available.

- Perforomist® (formoterol): Not recommended for addition to the PDL. Coverage would require PA with the criteria for approval being that the patient is unable to use a non-nebulized long-acting bronchodilator or anticholinergic inhaler (e.g. Serevent Diskus® or Foradil® Aerolizer or Spiriva® Handihaler) due to a physical limitation or the patient has documentation of side effect, allergy or treatment failure with a non-nebulized long-acting bronchodilator or anticholinergic [e.g. Foradil® (formoterol), Spiriva® (tiotropium) or Serevent® (salmeterol)]. A quantity limit of 2 vials/day was recommended.

*Public Comment:* No public comment.

**Board Decision:** The Board voted that the criteria for approval should be that the patient must have a diagnosis of COPD and the patient must be unable to use a non-nebulized long-acting bronchodilator or anticholinergic (Foradil®, Serevent® or Spiriva®) due to a physical limitation. The same criteria would also apply to the previously reviewed Brovana® (10/07). The recommended quantity limit of 2 vials/day was approved.

- Xyzal® (levocetirizine): Not recommended for addition to the PDL. Coverage would require PA with the criteria for approval being the patient is being treated for (1) allergic rhinitis or (2) chronic idiopathic urticaria and the patient has had a documented side effect, allergy, or treatment failure with loratadine (OTC) and cetirizine (OTC) and fexofenadine.

*Public Comment: Marie Sanchirico, Sanofi-Aventis* – Commented on several of the attributes of Xyzal® and comparative trials with other agents.

**Board Decision:** The Board unanimously approved the recommendations as described.

**7. Review of Newly-Developed/Revised Clinical Coverage Criteria:** *Diane Neal, R.Ph, (MHP)* (Public comment prior to Board action)

- Ophthalmics:Antihistamines (including Pataday® (olopatadine 0.2%):
  It was recommended that ketotifen 0.025 % (except Zaditor® RX) move to preferred status and that Elestat® and Patanol® approval require a previous trial of ketotifen 0.025 %. Pataday® was also added to the preferred products after step through ketotifen 0.025%. Emadine®, Optivar® and Zaditor® RX remain as PA required with the criteria for approval that the patient has had a documented side effect, allergy, or treatment failure to both Elestat® and Pataday®/Patanol®.

*Public Comment:* No public comment.

**Board Decision:** The updated table and revised clinical criteria were accepted as presented. The Board recommended that a quantity limit of the appropriate monthly quantity be added for each product.

- Remicade® in Crohn's Disease:
  It was recommended that the criteria for Remicade® be modified to no longer require a trial of Humira® first when the indication is Crohn's disease. There have been no comparative trials between the two products and it appears that gastroenterologists are more familiar and comfortable with the use of Remicade®. There are also several trials that show Humira® may be effective in patients who are either intolerant or have become resistant to Remicade®.

*Public Comment:* No public comment.

**Board Decision:** The revised criteria were unanimously accepted.

- Welchol® - new indication for improvement in glycemic control:
  It was recommended that Welchol® remain PA required including when used for the new indication of improvement in glycemic control. The drop in HgA1C was modest and there is a relative lack of data. It was recommended that the criteria for approval if being prescribed for additional improved glycemic control be that the patient must have been unable to obtain a satisfactory hemoglobin A1C reduction with metformin and one other oral anti-diabetic agent.

*Public Comment: Laurie Richie, Daiichi Sankyo* – Commented on the role of Welchol® as an add-on agent.

**Board Decision:** The Board approved the revised clinical criteria as recommended.

**8. New Drug Classes:**

No new drug classes this meeting.

**9. RetroDUR:** *Diane Neal, R.Ph, (MHP)*

- Botulinum Toxin (including FDA alert):
  A retrospective drug analysis of Botox® (botulinum toxin A) and Myobloc® (botulinum toxin B) was performed to review utilization and to evaluate the appropriateness of the current prior authorization status of Botox® and Myobloc® in light of the recent FDA warning. The prior authorization criteria for Botox® and Myobloc® were implemented on July 1, 2007. Data assessment for the 6 months prior to the botulinum toxins prior authorization implementation and the 6 months following the prior authorization implementation was conducted. All prior authorization requests were assessed and found to be appropriate. Overall, Botox® requests were approved for appropriate indications. All prior authorization approvals for non-FDA approved indications were given when deemed medically necessary. There was a 21 % decrease in the cost of paid claims for Botox® and Myobloc®. Utilization data for Botox® was decreased by 10 unique utilizers after the prior authorization implementation. It was recommended that Botox® and Myobloc® should continue to require prior authorization to exclude cosmetic and inappropriate uses. Although there was 0 % denial rate, no change in prior authorization status for these agents is recommended at this time due to high drug cost, potential cosmetic and/or off-label uses and the recent FDA warning for Botox® related death seen in children treated for cerebral palsy-associated limb spasticity.

*Public Comment:* No public comment.

**Board Decision:** The Board agreed that no change in prior authorization criteria was needed.

**10. New Drug Product Plan Exclusions (consent agenda topic):** *Diane Neal, R.Ph, (MHP)*

- New drug products released on the market are reviewed every 2 weeks by MedMetrics Health Partners to determine pharmacy benefit coding according to the current PDL. As approved by the DUR Board, drug products that appear to be illogical combinations, kits containing non-drug items or very expensive dosage forms where inexpensive alternatives exist are blocked. The presented table highlights drug products blocked from drug files dated 02/14/08 - 03/27/08. DUR Board members were asked to comment if they felt that a drug product should not be blocked.

*Public Comment:* No public comment.

**Board Decision:** None needed.

**11. Updated New-to-Market Monitoring Log:** *Diane Neal, R.Ph, (MHP)*

- This log shows new entries in the market highlighted in red. The log is informational only. Suggested dates for review are to be used as a guide only. The actual date of review will depend on the complexity of the agenda.

*Public Comment:* No public comment.

**Board Decision:** None needed.

**12. General Announcements:** *Diane Neal, R.Ph, (MHP)*
**FDA Safety Alerts**

- Fentanyl Patches – leaks:
  Not discussed at the meeting due to time constraints. The alert will be posted on the OVHA Pharmacy web site.

- Avandia® – new medication guide:
  Not discussed at the meeting due to time constraints. The alert will be posted on the OVHA Pharmacy web site.

- Tysabri® – liver injury:
  Deferred until next meeting.

- Spiriva®/Foradil® – correct use of powder capsules:
  It was recommended that this information be included in an upcoming OVHA Pharmacy Bulletin that is sent to all pharmacies as well as posting the alert on the OVHA pharmacy web site. It was noted by the Board that pharmacies have already received several alerts regarding this issue.

*Public Comment:* No public comment.

**Board Decision:** The Board agreed that no further direct to pharmacy communication was needed.

- Spiriva® – increased stroke risk:
  Not discussed at the meeting due to time constraints. The alert will be posted on the OVHA Pharmacy web site.

- Tamiflu® – neuropsychiatric events:
  Not discussed at the meeting due to time constraints. The alert will be posted on the OVHA Pharmacy web site.

- Tussionex® – life-threatening adverse events:
  The FDA informed healthcare professionals of life-threatening adverse events and death in patients, including children, who have received Tussionex®. The reports indicate that healthcare professionals have prescribed Tussionex® for patients younger than the approved age group of 6 years old and older, and more frequently than the labeled dosing interval of every 12 hours. Tussionex® is contraindicated for use in patients less than 6 years of age because of their susceptibility to life-threatening and fatal respiratory depression. Patients have administered the incorrect dose due to misinterpretation of the dosing directions, and have used inappropriate devices to measure the suspension. Overdose of Tussionex® in older children, adolescents, and adults has also been associated with life-threatening and fatal respiratory depression. It was recommended that in addition to the previously established criteria for Tussionex®, that additionally the patient must be 6 years of age or older and that a quantity limit of 60 ml be established. It was also recommended that the alert be posted on the OVHA pharmacy web site. The clinical criteria for cough and cold preparations were reviewed and it was recommended that PA be required for Age < 2 years old for all products (brand and generic).

*Public Comment:* No public comment.

**Board Decision:** The Board approved all MHP recommendations

- Prezista® - hepatotoxicity:
  Not discussed at the meeting due to time constraints. The alert will be posted on the OVHA Pharmacy web site.

**13. <u>Adjourn</u>:** Meeting adjourned at 9:12 p.m.

**Next DUR Board Meeting**
Tuesday, May 13, 2008
7:00 - 9:00 p.m.*
EDS Building, OVHA Conference Room
312 Hurricane Lane, Williston, VT
(Entrance is in the rear of the building)

* The Board meeting will begin at 6:30 p.m. and the Board will vote to adjourn to Executive Session to discuss Medicaid OBRA'90/Supplemental Rebates and Agreements as provided by 33 VSA § 1998(f)(2). The Executive Session is closed to the public.